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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,784	06/29/2001	Robert Martin Townsend	TJU-2498	1513

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EXAMINER	
MERTZ, PREMA MARIA	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 05/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/896,784	TOWNSEND ET AL.	
	Examiner	Art Unit	
	Prema M Mertz	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,14-16 and 26-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-4, 14-16, 26-31* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-17. Claims 1-4, 14-16, drawn to a peptide which mimics a loop on the γ-chain that either interacts with a cytokine or a γ-chain partner receptor chain of a heterodimeric cytokine receptor, wherein said peptide inhibits signal transduction mediated by cytokine-receptor binding of cytokines that bind to receptors that comprise a γ-chain, the polypeptide consisting of the amino acid sequence of SEQ ID NO:1-17, classified in Class 514, subclass 2.

Groups 18-34. Claims 26-29, drawn to a method of treating a patient treating a patient suffering from a disorder or condition of cytokine mediated cell growth, proliferation, function or activity comprising the step of administering to said patient a therapeutically effective amount of a peptide which mimics a loop on the γ-chain that either interacts with a cytokine or a γ-chain partner receptor chain of a heterodimeric cytokine receptor, wherein said peptide inhibits signal transduction mediated by cytokine-receptor binding of cytokines that bind to receptors that comprise a γ-chain, the polypeptide consisting of the amino acid sequence of SEQ ID NO:1-17, classified in Class 514, subclass 2.

Groups 35-51. Claims 30-31, drawn to a method of preventing a condition characterized by cytokine mediated cell growth, proliferation, function or activity in a patient identified as being at risk of such a condition comprising the step of administering to said patient a prophylactically effective amount of a peptide which mimics a loop on the γ-chain that either interacts with a cytokine or a γ-chain partner receptor chain of a heterodimeric cytokine receptor, wherein said peptide inhibits signal transduction mediated by cytokine-receptor binding of

cytokines that bind to receptors that comprise a γ-chain, the polypeptide consisting of the amino acid sequence of SEQ ID NO:1-17, wherein said patient is at risk of an allergic reaction, graft versus host disease or rejection of a transplant or graft classified in Class 514, subclass 2.

Should any one of the Groups from 1-51 be elected, Applicant is required to select one peptide (one amino acid sequence). Any change of amino acid residues at any one or more positions in the polypeptide sequence is considered, absent factual data to the contrary, a distinct polypeptide. Once one peptide sequence is selected, all other sequences will be withdrawn from consideration.

The inventions are distinct, each from the other because of the following reasons:

Inventions 1-17 are independent and distinct, each from the other, because each of the peptides are materially different products which are structurally and chemically different, capable of separate manufacture and use. The products in the different Groups are physically and chemically distinct from each other, and if patentable would support separate patents. Distinctness is further shown because a search of one of the peptides would not reveal art pertinent to the other and each of these products can be made and used without any one or more of the other products. Separate searches would be required for searching each of the peptide products eg. a search of the literature for the peptide of SEQ ID NO:1 would not necessarily reveal art for the peptide of SEQ ID NO:17. Therefore, each of the peptides are not related and are properly restrictable in accordance with MPEP. § 806.04 and MPEP. § 808.01.

Inventions 18-34 and 35-51 are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different starting materials,

process steps and goals. Inventions 18-34 are drawn to a method of inhibiting cytokine mediated cell growth by administering a peptide of amino acid sequence set forth in SEQ ID NO:1-17. However, Inventions 35-51 are drawn to a method of preventing the condition by administering a peptide of amino acid sequence set forth in SEQ ID NO:1-17. Therefore, the goals of inventions 18-34 and 35-51 are different and the starting materials are different.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their recognized divergent subject matter as defined by MPEP.. § 808.02, the Examiner has *prima facie* shown a serious burden of search (see MPEP.. § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

2. Claims 26-29, 30-31 are generic to a plurality of disclosed patentably distinct species comprising:

For claims 26-29, the species of disease are:

(a) lymphoma;

(b) leukemia;

© an allergic reaction;

(d) an autoimmune disease;

(e) graft versus host disease; and

(f) rejection of a transplant or graft.

For claims 30-31, the species of disease are:

(a) an allergic reaction;

(b) graft versus host disease; and

© rejection of a transplant or graft.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species of condition from claims 26-31 if any one of these claims is elected.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the

limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Prema Mertz whose telephone number is (571) 272-0876. The examiner can normally be reached on Monday-Friday from 7:00AM to 3:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (571) 271-0871.

Official papers filed by fax should be directed to (703) 872-9306. Faxed draft or informal communications with the examiner should be directed to (571) 273-0876.

Information regarding the status of an application may be obtained from the Patent application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prema Mertz

Prema Mertz Ph.D.
Primary Examiner
Art Unit 1646
April 26, 2004